



PTO/SB/08A/B (09-06)

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Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			Application Number	10/644,267-Conf. #6263	
			Filing Date	August 20, 2003	
			First Named Inventor	Heather L. Davis	
			Art Unit	1632	
			Examiner Name	A. M. Falk	
Sheet	1	of	3	Attorney Docket Number	O0277.70001US00

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/AMF/	A23*	US-4,710,463	12-01-1987	Murray et al.	
	A24*	US-4,803,164	02-07-1989	Hitzeman et al.	
	A25*	US-4,839,277	06-13-1989	Sugahara et al.	
	A26*	US-4,957,869	09-18-1990	Amot et al.	
	A27*	US-5,786,189	07-28-1998	Locht et al.	
	A28*	US-6,635,624	10-21-2003	Davis et al.	
	A29*	US-20020142978-A1	10-03-2002	Raz et al.	
/AMF/	A30*	US-20020192184-A1	12-19-2002	Carpentier	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
/AMF/	B7	WO-9728259-A1	08-07-1997	The Regents of the University of California		
/AMF/	B8	WO-2005004910-A2	01-20-2005	Intercell Ag		
/AMF/	B9	WO-2005039633-A1	05-06-2005	Mologen Ag		

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author ( in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/AMF/	C56	ALPAR et al., Potential of particulate carriers for the mucosal delivery of DNA vaccines. Biochem Soc Trans. 1997 May;25(2):337S.	
	C57	BRANDA et al., Immune stimulation by an antisense oligomer complementary to the rev gene of HIV-1. Biochem Pharmacol. 1993 May 25;45(10):2037-43.	
	C58	CALAROTA et al., Cellular cytotoxic response induced by DNA vaccination in HIV-1-infected patients. Lancet. 1998 May 2;351(9112):1320-5.	
	C59	CHEN et al., Protective immunity induced by oral immunization with a rotavirus DNA vaccine encapsulated in microparticles. J Virol. 1998 Jul;72(7):5757-61.	
	C60	DAHESHIA et al., Immune induction and modulation by topical ocular administration of plasmid DNA encoding antigens and cytokines. Vaccine. 1998 Jul;16(11-12):1103-10.	
	C61	DAVIS et al., Plasmid DNA expression systems for the purpose of immunization. Curr Opin Biotechnol. 1997 Oct;8(5):635-46.	
/AMF/	C62	ETCHART et al., Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin. J Gen Virol. 1997 Jul;78 ( Pt 7):1577-80.	

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			Examiner Name	A. M. Falk	
Sheet	2	of	3	Attorney Docket Number	O0277.70001US00

/AMF/	C63	FIELDS et al., Fields' Virology. 2001;1:1153.	
	C64	GALLICHAN et al., Specific secretory immune responses in the female genital tract following intranasal immunization with a recombinant adenovirus expressing glycoprotein B of herpes simplex virus. Vaccine. 1995 Nov;13(16):1589-95.	
	C65	GEISLER et al., Enhancement of cellular and humoral immune responses to hepatitis C virus core protein using DNA-based vaccines augmented with cytokine-expressing plasmids. J Immunol. 1997 Feb 1;158(3):1231-7.	
	C66	GRAMZINSKI et al., Immune response to a hepatitis B DNA vaccine in Aotus monkeys: a comparison of vaccine formulation, route, and method of administration. Mol Med. 1998 Feb;4(2):109-18.	
↓	C67	HALPERIN et al., A phase I study of the safety and immunogenicity of recombinant hepatitis B surface antigen co-administered with an immunostimulatory phosphorothioate oligonucleotide adjuvant. Vaccine. 2003 Jun 2;21(19-20):2461-7.	
/AMF/	C68	HALPERIN et al., Comparison of the safety and immunogenicity of hepatitis B virus surface antigen co-administered with an immunostimulatory phosphorothioate oligonucleotide and a licensed hepatitis B vaccine in healthy young adults. Vaccine. 2006 Jan 9;24(1):20-6. Epub 2005 Sep 12. Abstract Only.	
	<del>C69</del>	<del>HAYNES et al., Particle-mediated nucleic acid immunization. J Biotechnol. 1996 Jan 26;44(1-3):37-42. Duplicate</del>	
/AMF/	C70	HEDLEY et al., Microspheres containing plasmid-encoded antigens elicit cytotoxic T-cell responses. Nat Med. 1998 Mar;4(3):365-8.	
/AMF/	C71	JONES et al., Poly(DL-lactide-co-glycolide)-encapsulated plasmid DNA elicits systemic and mucosal antibody responses to encoded protein after oral administration. Vaccine. 1997 Jun;15(8):814-7.	
/AMF/	C72	KLINMAN et al., Therapeutic applications of CpG-containing oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Apr;8(2):181-4.	
	<del>C73</del>	<del>KUNOBER et al., DNA immunization induces antibody and cytotoxic T cell responses to hepatitis B core antigen in H-2b mice. J Immunol. 1996 May 15;156(10):3587-95. Duplicate</del>	
/AMF/	C74	LECLERC et al., The preferential induction of a Th1 immune response by DNA-based immunization is mediated by the immunostimulatory effect of plasmid DNA. Cell Immunol. 1997 Aug 1;179(2):97-106.	
	C75	LEE et al., Immuno-stimulatory effects of bacterial-derived plasmids depend on the nature of the antigen in intramuscular DNA inoculations. Immunology. 1998 Jul;94(3):285-9.	
	C76	MACGREGOR et al., First human trial of a DNA-based vaccine for treatment of human immunodeficiency virus type 1 infection: safety and host response. J Infect Dis. 1998 Jul;178(1):92-100.	
	C77	MCCLUSKIE et al., Novel strategies using DNA for the induction of mucosal immunity. Crit Rev Immunol. 1999;19(4):303-29.	
	C78	MCCLUSKIE et al., Novel adjuvant systems. Curr Drug Targets Infect Disord. 2001 Nov;1(3):263-71.	
	C79	MCCLUSKIE et al., Mucosal immunization with DNA vaccines. Microbes Infect. 1999 Jul;1(9):685-98.	
	C80	MCCLUSKIE et al., The role of CpG in DNA vaccines. Springer Semin Immunopathol. 2000;22(1-2):125-32.	
↓	C81	MCCLUSKIE et al., Route and method of delivery of DNA vaccine influence immune responses in mice and non-human primates. Mol Med. 1999 May;5(5):287-300.	
/AMF/	C82	PAYETTE et al., History of vaccines and positioning of current trends. Curr Drug Targets Infect Disord. 2001 Nov;1(3):241-7.	

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/AMF/	C83	ROMAN et al., Immunostimulatory DNA sequences function as T helper-1-promoting adjuvants. Nat Med. 1997 Aug;3(8):849-54.	
/AMF/	C84	RUBANYI, The future of human gene therapy. Mol Aspects Med. 2001 Jun;22(3):113-42.	
/AMF/	C85	TACKET et al., Phase 1 safety and immune response studies of a DNA vaccine encoding hepatitis B surface antigen delivered by a gene delivery device. Vaccine. 1999 Jul 16;17(22):2826-9.	
/AMF/	C86	UGEN et al., DNA vaccination with HIV-1 expressing constructs elicits immune responses in humans. Vaccine. 1998 Nov;16(19):1818-21.	
/AMF/	C87	WANG et al., Induction of antigen-specific cytotoxic T lymphocytes in humans by a malaria DNA vaccine. Science. 1998 Oct 16;282(5388):476-80.	
/AMF/	C88	WEERATNA et al., Reduction of antigen expression from DNA vaccines by coadministered oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Aug;8(4):351-6.	
/AMF/	C89	WEERATNA et al., CpG DNA induces stronger immune responses with less toxicity than other adjuvants. Vaccine. 2000 Mar 6;18(17):1755-62.	

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